

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE  
LITIGATION

MDL. NO. 1456

THIS DOCUMENT RELATES TO:

Civil Action No. 01-CV-12257- PBS

*County of Suffolk v. Abbott Laboratories, Inc.,  
et al.,*  
E.D.N.Y. Case No. CV-03-229

Judge Patti B. Saris

**Affidavit of Aaron D. Hovan Providing (1) Methodology And Documents Used  
To Estimate AWP Spread and (2) Additional Information Regarding Defendants**

Aaron D. Hovan, being duly sworn, deposes and says:

1. I am an associate at Kirby McInerney & Squire LLP, and submit this affidavit in response to the Court's October 26, 2004 Memorandum and Order ("Order") directing Suffolk to "disclose ... all documents upon which it relied in calculating the spreads, and provide ... a more definite statement of its method of calculation pursuant to Federal Rule of Civil Procedure 12(e)." Order at 4.

2. I submit this affidavit also to inform the Court that the majority of Suffolk defendants for whom the Court has stayed discovery at this juncture<sup>1</sup> have been named as defendants in other matters or are, in fact, the subject of government investigations related to the wrongdoing at issue in Suffolk's complaint. (See Exhibit A hereto) I submit this additional information given the Court's statement that, for these defendants, there are "no other allegations (e.g., government investigations or the company's own internal documents) to support a claim of fraudulent pricing". *Id.*

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<sup>1</sup> These are the "Suffolk 13" and Amgen, Inc., Chiron Corp., Fujisawa Pharmaceutical Company Ltd., Johnson & Johnson, Warrick Pharmaceuticals and Wyeth.

### **Suffolk's Method for Calculating Estimated Spreads**

3. Suffolk's pre-complaint review of publicly-available information revealed that the average wholesale prices ("AWPs") published in the *Redbook* for the prescription drugs paid for by Suffolk in 2001 generally exceeded retail prices by a significant margin. This raised red flags for Suffolk given that according to HHS and industry experts, the average prices paid to wholesalers are on average 27% lower than retail prices. Specifically, for prescription drugs "[i]n the United States, the average retail price is estimated to be 1.27 times the true average wholesale price." *See*, for example, John R. Graham & Beverley A. Robson, Prescription Drug Prices in Canada and the United States – Part 1: A Comparative Survey.<sup>2</sup> Suffolk confirmed the reasonableness of the 1.27 ratio with others, including Professor Steven Schondelmeyer of the University of Minnesota PRIME Institute,<sup>3</sup> and Andy Schneider, Esq., principal of the Washington D.C.-based Medicaid Policy, LLC.<sup>4</sup>

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<sup>2</sup> Annexed hereto at Exhibit J and available at <http://oldfraser.lexi.net/publications/pps/42> (last modified Aug. 23, 2000).

<sup>3</sup> Professor Schondelmeyer is among the AMCC plaintiff's experts in this MDL proceeding. Insofar as we know, defendants have not challenged his credentials as an expert within the context of the AMCC class certification motion.

<sup>4</sup> Mr. Schneider is a Princeton University and University of Pennsylvania Law School graduate. Mr. Schneider's clients include the Kaiser Commission on Medicaid and the Uninsured, for whom he co-authored, among other publications, *The Medicaid Resource Book* (July 2002), and *Financing the Medicaid Program: The Many Roles of Federal and State Matching Funds* (January 2004). Currently Mr. Schneider is preparing two reports about Medicaid fraud for the Taxpayers Against Fraud Education Fund. During his 17-year tenure on Capitol Hill, he has served as Counsel to the Subcommittee on Health and the Environment of the House Commerce Committee, then chaired by Henry Waxman (D-Calif.) He has also served as Policy Advisor for Medicaid to the House Democratic Policy Committee within the Office of Minority Leader Richard Gephardt (D-Mo.).

4. Thereafter, in an effort to estimate the amount by which the published AWP<sup>s</sup> exceeded the true AWP<sup>s</sup>, Suffolk calculated average retail prices for those dosages of its drugs for which it incurred the greatest Medicaid pharmacy costs in 2001.

5. To calculate these average retail prices, Suffolk surveyed three independent sources<sup>5</sup> of retail prices and averaged the data contained therein to arrive at a conservative average retail price for each drug. Within each source, when different per unit prices for multiple prescriptions were presented, Suffolk determined retail prices by dividing the price for the greatest quantity of units available by the number of units to arrive at a per unit price.

6. Suffolk then applied the 1.27 ratio to that average retail price to arrive at an “estimated true AWP.”

7. Suffolk then compared this “estimated true AWP” against the published AWP<sup>s</sup> less 10% (to account for New York’s statutory Medicaid reimbursement formula at the time) to arrive at an estimated overcharge, or “spread,” for each drug and dosage. The results of these comparisons are the estimated spreads that appear in the Suffolk Amended Complaint, and summarized in Exhibit B hereto.

8. Applying this methodology to 2003 and 2004 published AWP<sup>s</sup> and retail price data results in comparable estimated spreads for the Suffolk 2001 drugs. (See Exhibits C and D hereto).

**Documents Relied on in Calculating Estimated Spreads.**

9. Exhibit E lists the 100 drugs on which Suffolk incurred the greatest Medicaid Pharmacy costs in 2001.

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<sup>5</sup> Suffolk surveyed “drugstore.com”, “Eckerd.com” and “Costco.com” to obtain retail prices pre-2004. 2004 prices were obtained from “drugstore.com”, “Costco.com” and “familymeds.com”.

10. Exhibit F lists the 2003 Medicaid Pharmacy costs incurred by Suffolk County for these same drugs.

11. Exhibit G provides representative excerpts from the *Redbook* for one of the drugs for which Suffolk calculated an estimated spread (specifically, Albuterol AER 90 mcg). The *Redbook* provided Suffolk with all of the published AWP's utilized to calculate an estimated spread for the drugs at issue<sup>6</sup>.

12. Exhibit H contains representative printouts from the websites "Drugstore.com", "Eckerd.com", and "Costco.com," which sites served as the sources for all pre-2003 retail price data utilized by Suffolk in calculating the estimated spreads.

13. Exhibit I contains representative printouts from the websites "Drugstore.com", "Costco.com" and "Familymeds.com" which sites served as the sources for the 2004 retail price data utilized by Suffolk.

14. Exhibit J is Prescription Drug Prices in Canada and the United States -- Part 1: A Comparative Survey, by John R. Graham and Beverley A. Robson, available at <http://oldfraser.lexi.net/publications/pps/42/index.html>, which states at fn. 1 that "[i]n the United States, the average retail price is estimated to be 1.27 times the true average wholesale price."

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<sup>6</sup> Suffolk has not re-produced here every *Redbook* entry on which it relied to calculate an estimated spread for the Suffolk 2001 drugs. Suffolk can supplement this submission in that or any other regard if the Court so desires.

**Additional Information Regarding Defendants**

15. The majority of the defendants for whom the Court has stayed discovery pending this submission<sup>7</sup> have been named as defendants in other matters or are the subject of government investigations. *See* Exhibit A hereto.

16. Suffolk defendant Agouron has been sued in the Rockland and Westchester matters.

17. Suffolk defendant Amgen has been sued in the private class action Amended Master Consolidated Complaint ("AMCC") and by the City of New York and Counties of Rockland and Westchester.

18. In addition, Amgen has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services and the Attorneys General of the States of Pennsylvania and Wisconsin in connection with the wrongful conduct described in the Suffolk case.

19. Amgen also is the subject of a Senate Finance Committee investigation regarding whether it is improperly using the Nominal Price Exception to Medicaid Best Price reporting requirements.

20. It is clear also that Amgen knows its purchasers' profits depend on the AWP spread and reimbursement rates for drugs, and that Amgen's own sales and profits in turn depend on its customers' reimbursement payments and profits:

Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement rate could result in decreased sales of our products.

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<sup>7</sup> These are the "Suffolk 13" and Amgen, Inc., Chiron Corp., Fujisawa Pharmaceutical Company Ltd., Johnson & Johnson, Warrick Pharmaceuticals and Wyeth. *See* Order at 5.

In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payors . . . we believe that sales of Aranesp and Neulasta are and will be affected by government and private payor reimbursement policies. . . If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales or revenues . . . (Amgen 2002 Form 10-K at 43-44).

21. And, a 1993 OIG Report detailed how Amgen gave substantial year-end rebates to its customers based on their purchases of Epogen, one of the drugs at issue in the Suffolk matter. The report noted that Medicare and Medicaid beneficiaries did not receive the benefit of any rebates.

22. Suffolk defendant Barr has been sued by the Attorney General for the Commonwealth of Massachusetts, the City of New York and the Counties of Rockland and Westchester in connection with the same wrongful conduct as is at issue in the Suffolk matter.

23. Barr also is among the pharmaceutical companies under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

24. Suffolk defendant Berlex has been sued by the County of Westchester.

25. Suffolk defendant Biogen has been sued by the Counties of Rockland and Westchester

26. Suffolk defendant Eli Lilly has been sued by the City of New York and the Counties of Rockland and Westchester. Eli Lilly is also under investigation by the

House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements. Eli Lilly also is the subject of Senate Finance Committee investigation regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

27. Suffolk defendant Forest Pharmaceuticals has been sued by the City of New York and the Counties of Rockland and Westchester. In addition, Forest is the subject of a Senate Finance Committee investigation regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

28. Suffolk defendant Fujisawa has been sued in the AMCC and by the City of New York and the County of Westchester. In addition, in connection with the wrongful conduct described in the Suffolk matter, Fujisawa has been investigated by at least the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, and the Attorneys General for the State of Montana, Texas and California.

29. Suffolk defendant Ivax has been sued by the Attorney General for the Commonwealth of Massachusetts, the City of New York and the County of Westchester. In addition, Ivax Group is among the pharmaceutical companies now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

30. The Johnson & Johnson defendants have been sued in the AMCC and by the City of New York and the Counties of Rockland and Westchester. In addition, in connection with the wrongful conduct described in the Suffolk matter, the J&J

defendants have been investigated by the General Accounting Office and the Office of the Attorney General for the Commonwealth of Massachusetts.

31. J&J also is being sued by the Pennsylvania Attorney General in connection with the same wrongdoing at issue in the Suffolk matter.

32. J&J is among the pharmaceutical companies now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

33. J&J is the subject of a Senate Finance Committee investigation regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

34. Suffolk defendant Medimmune has been sued by the City of New York and the Counties of Rockland and Westchester.

35. Suffolk defendant Merck has been sued by the City of New York and Counties of Rockland and Westchester. In addition, in connection with the wrongful conduct described in the Suffolk matter, Merck is being investigated by the U.S. Department of Justice and the Attorney General of Texas.

36. Merck also is the subject of a Senate Finance Committee investigation regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

37. Suffolk defendant Purdue has been sued by the City of New York. Purdue is also among the pharmaceutical companies now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.



38. Suffolk defendant Sanofi-Synthelabo has been sued by the City of New York and the Counties of Westchester and Rockland. In addition, Sanofi is the subject of a Senate Finance Committee investigation regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

39. Suffolk defendant Warrick has been sued by the City of New York and the Counties of Westchester and Rockland.

40. In addition, in April 2004, Schering and Warrick announced that they were paying \$27 million to settle Medicaid fraud charges brought in 2000 by the Texas Attorney General. Investigators determined that Schering-Plough and Warrick provided and marketed the greatest "spread" of all drug companies selling Albuterol (one of the drugs paid for by Suffolk) in Texas, and thereby obtained the largest market share for Albuterol. Schering-Plough and Warrick sold a box of Albuterol to pharmacies for \$13.50, while it charged the Texas Medicaid program \$40.30, a 200% increase. *See* Cornyn Sues Three Drug Companies for Medicaid Fraud, Press Release by the Office of the Attorney General, State of Texas, September 7, 2000 ([www.oag.state.tx.us.gov](http://www.oag.state.tx.us.gov)).

41. According to the Texas Attorney General, "Schering/Schering-Plough marketed these 'Warrick' drugs reported by Schering/Schering-Plough and/or 'Warrick' drugs far below the false prices for the drugs referred by Schering/Schering-Plough and/or Warrick for reimbursement purposes. As a result, customers purchasing these 'Warrick' drugs from Schering knew they would receive, and did receive, windfall reimbursements as a direct result of the misrepresentations made by Schering and/or Warrick to reimbursers, including the Texas Medicaid Program." *See* Seventh Amended

Petition on the matter styled *The State of Texas ex. Rel. Ven-A-Care of Florida Keys, Inc. v. Warrick Pharmaceuticals Corp. et al.*, No. GV0022327 at ¶ 7.5

42. “Schering used the Warrick label and NDC number to implement a marketing program which induced customers to choose Warrick’s Albuterol, which was in fact Schering’s Proventil, over competing products based upon the large windfall reimbursements customers would receive.” *Id.* at ¶ 7.6

43. Schering also employed a group known as its Managed Care Sales Force who had as a part of their job responsibilities, the duty to call upon decision makers for HMOs, Pharmaceutical Benefits Managers, Hospitals and other Managed Care Organizations to explain the perspective of generic drug profitability on behalf of Schering and Warrick. Thus, employees and agents of Schering and combined with Warrick and marketed the spread on Warrick products and “bundled” Warrick and Schering products in a manner which was fraudulent and illegal. *Id.* at ¶ 8.9

44. Warrick cannot be heard to protest that the aforementioned conduct applies to Schering alone. Warrick could not exist without Schering/Schering-Plough. Per the Texas Attorney General, Warrick has only a handful of employees yet generates annual sales of over \$150M. Warrick depends on Schering’s manufacturing, distribution, accounting and administrative departments for all of these internal functions. Warrick apparently does not even employ persons with those traditional business responsibilities. Indeed, the only personnel Warrick allegedly employs are those who market and sell Schering’s generic products. Warrick’s business offices are within the office of Schering/Schering-Plough. Warrick does not conduct its corporate business in Reno, Nevada as letterhead represents. Instead, Schering/Schering-Plough and Warrick operate

from the same office space in New Jersey, use the same computer systems, telephone, employees, and centralized departments, and apparently use each other's letterhead interchangeably. These companies acted as one rather than two independent drug manufacturers.

45. On July 16, 2004, it was announced that Warrick's parent Schering agreed to pay \$350 million in fines and plead guilty to federal criminal charges that it cheated Medicaid by failing to comply with Medicaid rebate requirements.


46. This followed a 2003 announcement by Schering that it was the subject of a federal grand jury investigation and criminal investigation led by the U.S. Attorney for District of Massachusetts. The investigation concerned (i) providing remuneration, such as drug samples, to providers to induce the purchase of Schering products for which payment was made through federal health care programs; (ii) selling misbranded or unapproved drugs; (iii) submitting false wholesale pricing information for its pharmaceutical products to the government; and (iv) destroying evidence and obstructing justice relating to the government's investigation. *See* Schering-Plough Press Release dated May 30, 2003, "Schering Plough Provides Update on Previously Reported Investigation by U.S. Attorney for District of Massachusetts." Schering's Form 10-K for the year 2000 stated that this investigation focused on "whether the AWP set by pharmaceutical companies for certain drugs improperly exceeds the average prices paid by dispensers... and other pricing and/or marketing practices."

47. Both Schering and Warrick are among the pharmaceutical companies now under investigation by the House of Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

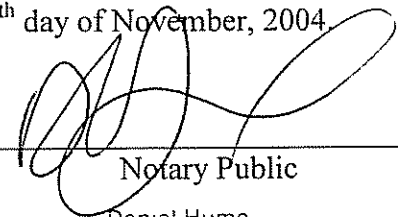
48. Finally, in Warrick's answer to the AMCC (at ¶ 3), Warrick admits that AWP's for its medicines published in trade publications are typically higher than the prices ultimately paid by providers purchasing such medicines from wholesalers and distributors. And, Warrick admits that it communicated with industry compendia regarding AWP's for its products and that the published AWP's for most drugs are higher than the actual prices provided to wholesalers. *Id.*

49. Schering, including Warrick, is also under investigation by the Attorneys General of California, Massachusetts, Minnesota, Montana, Ohio, Pennsylvania and Wisconsin in connection with the wrongdoing discussed in the Suffolk complaint.

50. Suffolk defendant Wyeth has been sued by the California Attorney General, the City of New York and the Counties of Westchester and Rockland. In addition, Wyeth is the subject of a Senate Finance Committee investigation regarding whether it is inappropriately using the Nominal Price Exception to the Best Price reporting requirements.

  
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Aaron D. Hovan

Sworn to before me this  
16<sup>th</sup> day of November, 2004.

  
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Notary Public  
Daniel Hume  
Notary Public, State of New York  
No. 31-5056750  
Qualified in New York County  
Commission Expires 3/11/06

**CERTIFICATE OF SERVICE**

I hereby certify that on the 16<sup>th</sup> day of November, 2004, I caused a true and correct copy of the County of Suffolk's Affidavit of Aaron Hovan Providing (1) Methodology and Documents Used To Estimate AWP Spread and (2) Additional Information Regarding Defendants to be served on all counsel of record by electronic service via Verilaw's Electronic Service System pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL No. 1456

/s/ Aaron D. Hovan

Aaron D. Hovan

Kirby McInerney & Squire L.L.P

830 Third Avenue, 10<sup>th</sup> Floor

New York, NY 10022

(212) 371-6600